K091871

510(k) Summary
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12-Aug-09

OCT 23 2009

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Official Contact: Ernest Koppon – Quality and Regulatory Manager

Proprietary or Trade Name: DK50 DS

Common/Usual Name: Portable air compressor

Classification Name/Code: BTI – portable air compressor
21 CFR 868.6250

Device: DK50 DS

Predicate Devices: K060781 – Ekom Model DK50 D
K041406 – Newport Model C250

Device Description:
The Ekom model DK50 DS is a portable air compressor designed to supply air to medical equipment, i.e., ventilators.

The Model DK50 DS contain an oil-free piston compressor driven by a low maintenance single phase electric motor. Compressed air is cooled where condensed water is separated into a vessel. Incoming air passes through 2 filters and undergoes double filtration as it passes through the system. Constant output pressure is maintained by a pressure regulator. There is a built-in air tank which allows peak air consumption of 200 Lpm.

The device may be used as a standby source of air. In this configuration, the respiratory equipment is supplied with compressed air from the facilities central air distribution. Air pressure in this central distribution is sensed by the Ekom pressure sensor. If the pressure is sufficient, the compressor stays in the STANDBY mode. If the pressure falls the compressor automatically starts and becomes the main air supply.

When the compressor is used as the main source, the control unit determines its operation according to the current need for air. If air consumption is zero, the device switches to STANDBY.

The compressor is equipped with indicators for output pressure, operation hours, power status, drying efficiency and battery condition as well as acoustic and optic alarms to warn of high operating temperature, low output pressure and loss power.

Indications for Use:
Indicated for supplying compressed air for medical ventilators.

Environment of Use:
Hospital or sub-acute institution

Summary of substantial equivalence:

Model Name: / **Specification**	**Modified device DK50 DS**	**Unmodified device Predicate – K060781 DK50 D**
Output flow	Max. 40 Lpm	Max. 40 Lpm
Peak Flow	200 Lpm for 2 sec	200 Lpm for 2 sec
Power	120V /60 Hz	120V /60 Hz
Nominal current (amps)	5.6 A	5.6 A
Air filtration	5 micron	5 micron
Pressure dew point @ 40 Lpm 20^{0}C	5^{0}C below ambient temperature	5^{0}C below ambient temperature
Outlet connection	DISS	DISS
Sound level	≤ 51 dB(A)	≤ 51 dB(A)
Mode of operation	Continuous – S1	Continuous – S1
Separation of condensed water	Automatic	Automatic
Operating pressure of safety valve	8 bar (116 psig)	8 bar (116 psig)
Adjustment of pressure output	Pressure regulator	Pressure regulator
Alarm for cooling failure / high temperature	Acoustic and optical if increase in internal temperature > 80°C (176°F)	Acoustic and optical if increase in internal temperature > 80°C (176°F)
Automatic turn-on pressure	When central distribution pressure < 2.8 bar (40.6 psig)	When central distribution pressure < 2.8 bar (40.6 psig)
Output pressure	3 bar (43.5 psig)	3 bar (43.5 psig)
Output pressure indicator	Display	Pressure gauge
Alarm – loss of power	Yes	No, but instructions require connection to equipment with this alarm
Indication of drying	LEDs	Pressure gauge
Alarm for low pressure	Internal when output pressure < 2.1 bar (30 psig)	None instructions require connection to equipment with this alarm
Air tank capacity	2L	5L
Pressure range	5 to 6.5 bar (72.5 – 94 psig)	5 to 7 bar (72.5 – 101.5 psig)
Dimensions (mm)	510 x 480 x 470 mm (17.5 x 14 x 17 in.)	500 x 530 x 870mm 16 x 17 x 30.5 in
Weight	30 kg (66 lbs)	46 kg (101 lbs)

Table 1 – Table of the Similarities and Modifications from Predicate vs. new Model

Model Name:	**New device DK50 DS**	**Predicate – K041406 Newport Model 250C**
Specification		
Alarm – loss of power	Yes	Red light and audible alarm when no power
Alarm for low pressure	Triggers when output pressure < 2.1 bar ((30 psig)	Triggers at 30 ± 2 psig (2.0 ± 0.13 bar)

Table 2. Comparison of Alarms between Predicate and Proposed Model

It is our view that there are no significant differences that affect the safety or effectiveness of the intended device as compared to the predicate device.

Substantial Equivalence

The Ekom DK50 DS is viewed as substantially equivalent to the predicate devices because:

Indications –

- Identical to predicate – K060781 – Ekom DK50 D

Technology –

- Similar technology used –
  - K060781 – Ekom DK50 D
  - K041406 – Newport Model C250 for alarms

Materials –

- The materials in patient contact are identical to predicate device, K060781 – Ekom DK50 D.

Environment of Use –

- Identical to predicate – K060781 – Ekom DK50 D

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Ekmo S.R.O.
C/O Mr. Paul E. Dryden
President
ProMedic, Incorporated
24301 Woodsage Drive
Bonita Springs, Florida 34134-2958

OCT 23 2009

Re: K091871
Trade/Device Name: Model DK50 DS
Regulation Number: 21 CFR 868.6250
Regulation Name: Portable Air Compressor
Regulatory Class: II
Product Code: BTI
Dated: September 22, 2009
Received: September 23, 2009

Dear Mr. Dryden:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for

Susan Runner, D.D.S., M.A.
Acting Division Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K091871 (To be assigned)

Device Name: Model DK50 DS

Indications for Use:

Indicated for supplying compressed air for medical ventilators.

Prescription Use XX (Part 21 CFR 801 Subpart D) **or** **Over-the-counter use __** (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

L Schultheis

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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